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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,641	11/28/2001	Vincent Mutel	20772	5346

151 7590 02/12/2003

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

SAEED, KAMAL A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,641

Applicant(s)

MUTEL ET AL.

Examiner

Kamal A Saeed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

Claims 1-31 are pending in this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 10, 11 and 13-20, are drawn to compounds and pharmaceutical compositions of compounds of **Formula I-A**, as defined in claim 13, variously classified, in classes 514, 546, 548, 549 and several subclasses.
- II. Claims 10, 12, 21, and 24-26 are drawn to compounds and pharmaceutical compositions of compounds of **Formula I-B-1**, as defined in claim 21, variously classified, in classes 514, 546, 548, 549 and several subclasses.
- III. Claims 10, 27, 30 and 31, are drawn to compounds and pharmaceutical compositions of compounds of **Formula I-B-2** as defined in claim 27, variously classified, in classes 514, 546, 548, 549 and several subclasses.
- IV. Claims 1-9, 22, 23, 28 and 29 methods of use of compounds variously classified, in classes 514, 546, 548, 549 and several subclasses.

The inventions are distinct, each from the other because of the following reasons:

The inventions of group I – III are unrelated and are directed to distinct compounds.

These compounds are distinct, each from the other, because they differ in structure and/or element so as to be patentably distinct and a prior art reference anticipating but one of the groups would not render obvious the other groups under 35 U.S.C. 103.

Invention Groups I-III and Invention Group II are related as product and method of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

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product or (2) the product as claimed can be used in a materially different method of using the product (MPEP 806.05(h)). In the instant case, the product as claimed can be used in a materially different method of using the product as demonstrated throughout the specification and in claims 1-9, 22, and 23 which are directed to several methods of using the product, for example treating pain, anxiety or depression. Therefore a separate search considerations are involved, which would impose a burden if unrestricted.

Accordingly, along with the election of one of the above groups, the following action is also taken.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising, for example, the compounds of (1) Example 10, page 30, Example 43, page 41, Example 32, etc., (2) a method of treating pain, depression etc using the compounds as in Example 10, etc. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purpose as indicated is proper.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Upon the election of a single disclosed species (e.g. Example, page number and structural depiction), a generic concept, inclusive of the elected species, will be identified by the Examiner for examination. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon.

In accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with method of use claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised the process of use are amended during prosecution to maintain either dependency on the product claims or to otherwise include limitations of the product claims.

Failure to do so may result in a loss of the right to rejoinder.

A telephone call was made to Arthur D. Dawson, on 02/02/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

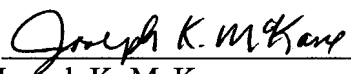
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed whose telephone number is (703) 308 4592. The examiner can normally be reached on M-F 8:00 AM- 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (703) 308 4537. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308 7921 for regular communications and (703) 308 7921 for After Final communications.

Kamal Saeed, Ph.D.
February 6, 2003



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1